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IN THE
SUPREME COURT
OF THE UNITED STATES
October Term, 1984

KENNETH W. KIZER, M.D., M.P.H., Director of the Department of Health Services; GEORGE DEUKMEJIAN, Governor of the State of California; STATE OF CALIFORNIA, a political entity,
Petitioners,

vs.

ANNA JENESKI, WILLIAM SWAIN, EDITH PANTILLA, and ARTHUR COLVIN,
Respondents.

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

COUNTERSTATEMENT OF QUESTIONS PRESENTED

Because this case is presented after a ruling granting respondents' request for preliminary injunctive relief, there are no issues which have been finally adjudicated by any court below which are now being presented to this Court.

Rather, the sole question presented to this Court is whether the California Court of Appeal properly found that respondents met their burden of demonstrating entitlement to preliminary injunctive relief, *i.e.*, (1) that pending trial the irreparable harm that respondents would suffer from denial of certain medications determined to be medically necessary by their treating physicians outweighs the expense petitioners will incur in providing such medications to indigents and medically needy, and (2) that there is a sufficient likelihood that respondents will prevail on the merits at trial.

The Court of Appeal's decision subsumes findings resolving the questions listed below, although these findings are not controlling on the ultimate issue of whether preliminary injunctive relief was properly granted since these questions relate only to the satisfaction of the second criteria for obtaining injunctive relief (*i.e.*, likelihood of success on the merits) and do not address numerous other substantive grounds[1] presented by respondents in support of

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[1] The Court of Appeals found it unnecessary to address the following issues raised by respondents and amicus in support of their motion, each of which constitutes an independent and adequate state or federal ground for concluding there is sufficient likelihood that respondents will prevail at trial:

1. The trial court erred in failing to maintain a preliminary injunction in effect since the regulation implementing the proposed cutbacks violates the "sufficiency requirement" of 42 C.F.R. §440.230(b).

2. The regulation implementing the proposed cutbacks violates the "simplicity of administration" and "best interest of the patient" requirements of 42 U.S.C. §1396(a)(19).

3. The subject regulation violates Title XIX of the Social Security Act's mandate of equality and therefore is invalid.

4. The subject regulation deprives Medi-Cal patients of the rights secured to them by 42 U.S.C. §1396(a)(19), in violation of the equal

their motion for preliminary injunction:

1. Whether implementation of legislatively mandated cutbacks in pharmaceutical services provided to Medi-Cal[2] recipients violates federal law by arbitrarily denying or reducing the amount, duration or scope of services to eligible recipients because of diagnosis, type of illness or condition;

2. Whether the prior authorization system (known as the "TAR" system), employed by the State of California as a utilization control of services provided to Medi-Cal recipients, is legally flawed because it does not provide for pre-denial hearings;

3. Whether the TAR system, as it applies to the prescription drug program, is legally flawed because it permits pharmacists to substitute their judgment for the medical judgment of the recipient's treating physician as to the medical necessity of prescribed drugs.

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protection clause of the Fourteenth Amendment.

5. The subject regulation is void and contrary to the law in that it discriminates against eligible Medi-Cal recipients based purely on economic disability.

6. Section 53(2) of AB 799 conferred upon the director of Health Services an unconstitutional delegation of power.

7. The subject regulation is an unconstitutional restraint on those Medi-Cal patients exercising their fundamental rights guaranteed by the California Constitution.

8. Petitioners' failure to consult the State Medical Advisory Committee as required by federal law requires invalidation of the drug formulary changes.

9. The prior approval system for certain pharmacy categories lacks the standards required by federal law.

Pet. App., pp. 9-11.

[2] Medi-Cal is the name given to the Medicaid program in California.

COUNTERSTATEMENT OF THE CASE

This case involves an action brought by Medi-Cal recipients to enjoin petitioners from implementing legislatively mandated cutbacks in pharmacy services provided by the Medi-Cal program. The implementing regulations (Title 22, Cal. Admin. Code §§ 59998-59999) eliminated six categories of drugs from the Medi-Cal program altogether, and put four other categories of drugs, which had previously been available on the Medi-Cal formulary without prior authorization, on a list for which prior authorization was required as a condition of Medi-Cal reimbursement.

Respondents moved for a preliminary injunction, raising 13 issues in support of their motion including, *inter alia*, that petitioners, through these cut-backs, had eliminated from the Medi-Cal program virtually all drugs necessary to treat particular classes of disorders, thereby reducing services to Medi-Cal recipients on the basis of diagnosis, illness or condition in violation of 42 C.F.R. §440.230(c).[3] As independent justification for injunctive relief, respondents argued that the prior authorization system (known as the "TAR" system) is legally flawed because it fails to offer pre-denial hearings to beneficiaries for whom TAR requests were denied, and further because it allows pharmacists to substitute their judgment for that of a beneficiary's treating physician as to whether a particular drug is medically

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[3] 42 C.F.R. §440.230(c) states as follows:

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration or scope of a *required service under §§440.210 and 440.220* to an otherwise eligible recipient solely because of the diagnosis, type of illness or condition. (Emphasis supplied.)

necessary to treat the beneficiary's illness.[4] Respondents contended that, by subjecting certain drugs to such prior authorization system, petitioners are improperly limiting or denying pharmacy services to Medi-Cal recipients.

The trial court denied respondents' motion for preliminary injunction, but the Court of Appeal reversed, ruling that the trial court abused its discretion in denying respondents' motion. Specifically, the Court of Appeal found that respondents satisfied both criteria for obtaining a preliminary injunction, *i.e.*, that the irreparable harm which Medi-Cal beneficiaries would suffer by denial of medically necessary drugs outweighed the harm petitioners would suffer through incurring the expense of such drugs, and that respondents demonstrated a sufficient likelihood of prevailing on the merits based upon the arguments described above. The Court of Appeal specifically noted that its decision *did not* constitute "an adjudication of the ultimate rights in controversy" as to the issues discussed above (Pet. App. A., p. 12). The court further stated that, because it agreed with respondents that the TAR system is legally invalid, it need not address the other issues raised by respondents in support of their motion for preliminary injunction (Pet. App. A., pp. 21-22).

SUMMARY OF ARGUMENT

Petitioners fail to present any grounds justifying the grant of certiorari in this case. Because the decision which petitioners ask this Court to review involves the granting of

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[4] Respondents presented nine additional independent and adequate state and federal grounds for relief which the Court of Appeal found it unnecessary to address. *See* footnote 1, *supra*.

a motion for preliminary injunction, where no final judgment on any issue has been rendered and where a vast number of issues remain undecided in any fashion, the relief which petitioners seek from this Court is premature and unwarranted.

Petitioners challenge the Court of Appeal's application of the rule of *White v. Beal*, 555 F.2d 1146 (3rd Cir. 1977), *i.e.*, that the non-discrimination provisions of 42 C.F.R. §440.230(c) apply equally to so-called optional and mandatory Medicaid services. Petitioners base this contention on a district court case which misinterprets the regulation in question and which, for that reason, is inconsistent with all other federal and state courts that have addressed the issue after *White v. Beal*.

In challenging the Court of Appeal's other findings, *i.e.*, that the prior authorization system is legally flawed by failing to provide pre-denial hearings and by allowing pharmacists to overrule physician decisions concerning medically necessary treatment, petitioners do not dispute the legal basis underlying the Court of Appeal's findings, but merely attempt to re-argue the evidence relating to these issues. In doing so, petitioners ignore many relevant facts, and grossly misstate others. Similarly, petitioners' assertion that TAR denials are neither arbitrary nor harmful to patients in need of the requested medication is totally contrary to the evidentiary record of this case.

ARGUMENT IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

A. The Issues Presented by This Case Are Not Appropriate for Review by Writ of Certiorari.

The principal issue presented by this case is whether the Court of Appeal properly found that respondents are entitled to preliminary injunctive relief until such time as a trial on the merits is held.[5] Petitioners do not assert, as a reason in support of their petition, that the Court of Appeal erroneously found that the irreparable harm suffered by respondents, who are denied medically necessary drugs, outweighs any harm suffered by petitioners in providing these medications to Medi-Cal beneficiaries. *See* Pet., p. 5, n. 6. The Court of Appeal cites with approval the following language from *Bass v. Richardson*, 338 F.Supp. 478, 489 (S.D.N.Y. 1971) as the basis of its finding:

> The State cannot prevail on the balance of incredible human suffering which the amendments to this program would create. The injury to those whose health is maintained on the slenderest chemical balance provided through medication is not merely irreparable; it is ultimate.

Pet. App., p. 14.

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[5] The Court of Appeal, in its opening discussion paragraph, acknowledges that the trial court's granting or denial of a preliminary injunction does not amount to an adjudication of the ultimate rights in controversy, but rather reflects a balancing of the respective equities of the parties in light of the probability of plaintiffs ultimately prevailing in the case. Pet. App. A., p. 12, quoting *Continental Baking Co. v. Katz*, 68 Cal.2d 512, 528 (1968).

Petitioners' failure to address the Court of Appeal's conclusion on irreparable harm is fatal to their request for relief from this Court, since this finding constitutes an independent and adequate state ground supporting the grant of injunctive relief. The law in California, as stated by the Court of Appeal, is that when considering a motion for preliminary injunction " 'in the last analysis the trial court must determine which party is more likely to be injured by the exercise of its discretion [citation] and it must then be exercised in favor of that party [citation].' " *Continental Baking Co. v. Katz*, 68 Cal.2d 512, 528 (1968). *See* Pet. App. A., p. 12. Because the Court of Appeal considered the balance of relative hardships to weigh so heavily in favor of respondents, it was clearly justified in granting the preliminary injunction if it found respondents made a reasonable showing that they were likely to succeed at trial. Unless petitioners can now establish that there is absolutely no basis on which it can be found that respondents have a reasonable likelihood of prevailing on the merits, petitioners cannot demonstrate to this Court that the preliminary injunction was erroneously granted.

Petitioners do not, however, undertake the task of arguing that there was no basis justifying the preliminary injunctive relief granted to respondents. Instead, petitioners challenge only the Court of Appeal's findings on three of the available bases for ruling in respondents' favor.[6] Petitioners' arguments do not, therefore, resolve the ultimate question of whether respondents are entitled to a preliminary injunction.

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[6] Petitioners totally ignore the remaining nine independent and adequate grounds asserted in support of respondents' motion for injunctive relief. *See* footnote 1, *supra*.

Moreover, assuming *arguendo* that petitioners had successfully undertaken to establish that there was no basis for concluding that there is a reasonable likelihood that respondents will succeed on the trial in this action, it does not follow that the Court of Appeal's decision to grant respondents' motion for a preliminary injunction was erroneous. "[T]he possibility that the party obtaining a preliminary injunction may not win on the merits at the trial is not determinative of the propriety or validity of the trial court's granting the preliminary injunction." *B.W. Photo Utilities v. Republic Molding Corporation*, 280 F.2d 806, 807 (9th Cir. 1960). As discussed above, the court's assessment of the probability that the moving party will ultimately succeed is only one criteria considered in ruling on a motion for preliminary injunction. Indeed, it is the fact that the court has such broad discretion to consider numerous factors in deciding whether to grant or deny a preliminary injunction that makes its determination on this question inappropriate for review by this Court.

In addition, it is respectfully submitted that the reasons advanced by petitioners in support of their petition are not of a character which this Court will consider in the exercise of its discretion. *See* Rules of the Supreme Court of the United States, Rule 17. Specifically, petitioners do not contend that the Court of Appeal decided a federal question in a way in conflict with another state or federal appellate court, nor that this case involves any novel or important question of law which requires clarification by this Court.

Rather, the arguments raised by petitioners deal largely with pragmatics and fiscal concerns and, therefore, belong more properly with the California Legislature which can weigh the various options, information and social issues that exist in the area of providing health care to indigents. As to

the Court of Appeal's specific findings, they are all fully supported by and consistent with each federal and state appellate court which has considered the issues discussed by the Court of Appeal.

For these reasons, it is respectfully submitted that review by this Court of the Court of Appeal's decision is improper. In addition, for the reasons set forth below, it is respectfully submitted that the Court of Appeal properly decided the questions of law addressed in its opinion.

Following is a rebuttal to the three arguments raised by petitioners which, again, respondents contend cannot be dispositive of the issue of whether respondents are entitled to injunctive relief.

B. The Court of Appeal Is Correct in Its Finding that 42 C.F.R. §440.230(c) Applies to Changes in Medi-Cal's Prescription Drug Program.

Petitioners' primary argument in support of their petition is that the Court of Appeal erred in finding that 42 C.F.R. §440.230(c), which prohibits reductions in "required [Medicaid] services" on the basis of diagnosis or illness, applies to the prescription drug component of the Medi-Cal Program, a so-called "optional" Medi-Cal service.[7] Petitioners further make the unsubstantiated assertion that this particular finding of the Court of Appeal, if not reviewed

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[7] Petitioners' assertion (Pet., p. 11) that "Petitioners were successful in convincing the trial court that federal regulation [42 C.F.R. §440.230(c)] had no applicability to an optional service such as the prescription drug program" is incorrect. The trial court made no express finding whatsoever on the applicability of 42 C.F.R. §440.230(c) to the prescription drug program or the cutbacks in question.

by this Court, will encourage legislatures throughout the nation to discontinue the prescription drug component in its entirety. Pet., p. 16.

Petitioners are wrong on both counts. With respect to their analysis of the scope of 42 C.F.R. §440.230(c), petitioners' argument that *White v. Beal*, 555 F.2d 1146 (3d Cir. 1977) is no longer good law due to changes in the regulation it interprets is ill-founded. A comparison of current 42 C.F.R. §440.230(c) to its predecessor shows that the changes in question, *i.e.*, the substitution of the phrase "required services for the categorically needy and the medically needy," was strictly cosmetic.[8] 42 C.F.R. §§440.210 and .220 are titled respectively "Required Services for the Medically Needy," and the services which are "required" for the "categorically needy" and the "medically needy" are virtually unchanged today from the time *White v. Beal* was decided.[9] Thus, the rule of *White v.*

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[8] According to the opinion of the *White* court, the predecessor to 42 C.F.R. §440.230(c), former 45 C.F.R. §249.10(a)(5)(i), provided in pertinent part as follows:

With respect to the *required services for the categorically needy... and the medically needy...* the State may not arbitrarily deny or reduce the amount, duration, or scope of, such services to an otherwise eligible individual solely because of the diagnosis, type or illness of condition. *White v. Beal, supra*, 555 F.2d at 1151.

[9] 42 C.F.R. §440.210, entitled "Required Services for the Categorically Needy," provides as follows:

A state plan must specify that, as a minimum, categorically needy recipients are provided the services as specified in §§440.10 through 440.50, 440.70, and (to the extent nurse-midwives are authorized to practice under State law or regulation) 440.165.

42 C.F.R. §440.220, entitled "Required Services for the Medically Needy," provides in pertinent part as follows:

A state plan that includes the medically needy must specify that the medically needy are provided, as a minimum, the following services...

Beal remains applicable today.

Indeed, with only one known exception, the federal and state courts interpreting 42 C.F.R. §440.230(c) have shown no hesitation in following the rule of *White v. Beal* after the amendment of the regulation. *See Simpson v. Wilson*, 480 F.Supp. 97, 102 (D.Vt. 1979) (42 C.F.R. §440.230(c) applied to "optional" eyeglass component of Vermont Medicaid plan); *Hodgson v. Bd. of County Com'rs, County of Hennepin*, 614 F.2d 601, 608 (8th Cir. 1980) ("Once a state designates services it will subsidize, it may distinguish between eligible and ineligible recipients *only* on the basis of their degree of medical necessity"); *see also Helen Vander Steen v. Dept. of Health and Social Services of the State of Wisconsin*, No. 84-047, Ct. of App. of Wisconsin (1984), Slip Limited Precedent Opinion at p. 3 (attached hereto as Appendix A) (42 C.F.R §440.230(c) applied to "optional" intermediate care facilities component of Wisconsin Medicaid plan), which states:

(d)...

(1) The services contained in §§440.10 through 440.50 and (to the extent nurse-midwives are authorized to practice under State law or regulation) 440.165; or

(2) The services contined in any seven of the sections in §§440.10 through 440.165.

At the time of *White v. Beal*, required services for the categorically needy included at least the first five items set forth in 42 U.S.C. § 1396d(a), and required services for the medically needy included at least the first five items or any seven of the sixteen items set forth in 42 U.S.C. § 1396d(a). *White v. Beal, supra*, 444 F.2d at 1152, n.6. These sixteen items are additionally listed as 42 C.F.R. §§440.210 through .165, and a review of 42 C.F.R. §§440.210 and .220, set forth above, show that they require the same minimum services to be provided the categorically and medically needy respectively as at the time of *White v. Beal*.

> Intermediate care facilities are a required service. While such services do not form part of a state Medicaid plan's mandatory nucleus for the categorically needy, 42 U.S.C. § 1396a(1)(10)(4) [sic] (1983), such services are required by the Wisconsin plan....In *White v. Beal*, 555 F.2d 1146 (3d Cir. 1977), the regulation was similarly applied to a service required by the Pennsylvania plan that was not specifically mandated by the federal statute. Moreover, intermediate care facilities are also required for the medically indigent [under the Wisconsin plan], and federal law precludes giving less generous aid to the categorically needy than to the medically needy. *Sinclair v. Dept. of Health and Social Services*, 77 Wis.2d 322, 334, 253 N.W.2d 245, 250 (1977); 42 U.S.C. § 1396a(a)(10)(B) (1983).

The only case to not follow *White v. Beal* is *Ledet v. Fischer*, 548 F.Supp. 775 (M.D.La. 1982), the district court case upon which petitioners rely. However, a review of *Ledet* indicates that the court's interpretation of the meaning of "required services" under 42 C.F.R § 440.230(c) is patently erroneous. Specifically, the court in *Ledet* mistakenly interpreted "required service" simply and solely by reference to the services which must be provided to categorically needy under 42 C.F.R. § 440.210, failing to include or accord any significance to the services required to be provided the medically needy under 42 C.F.R. § 440.220. *See Ledet v. Fischer, supra*, 548 F.Supp. at 786.[10]

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[10] Petitioners repeat this same reasoning error in their petition. *See* Pet., p. 12, n. 9. After first itemizing those minimum services which are required for the categorically needy under 42 C.F.R. § 440.210, petitioners dismiss 42 C.F.R. § 440.220 by stating that it "similarly does

Such an analysis is grossly mistaken for, by its very failure to specify any particular service which must be provided to the medically needy, 42 C.F.R. §440.220 necessarily denotes each and every service actually offered to the medically needy, whether mandatory or optional for the categorically needy, to be a "required service for the medically needy." Were it otherwise, no service under 42 C.F.R. §440.220 could ever be a "required" one, even though the regulation is titled "Required Services for the Medically Needy." Further, the reference in 42 C.F.R. §440.230(c) to 42 C.F.R. §440.220 would be superfluous. As a cardinal rule of statutory interpretation, statutes must be interpreted so as to give meaning to every phrase and word therein.

It is this simple logic that underlies the *White* decision, and which has no doubt additionally guided the Court of Appeal in reaching its finding.[11] Petitioners' analysis, mistaking the significance of a cosmetic amendment and failing as it does to take into account key provisions of the regulatory language it purports to explain, is simply wrong.

The second prong of petitioners' argument, *i.e.*, that legislatures will be encouraged to eliminate the prescription drug program in its entirety on accouant of the Court of Appeal decision, is both irrelevant speculation and meritless. As a practical matter, legislatures are well aware that medications are cost-effective, that reductions in Medicaid medication benefits to ill persons who cannot afford to purchase medications on their own will result in

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not include the requirement that prescription drug services be provided."

[11] Petitioners do not contest the fact that the California Medi-Cal Program provides prescription drug services as a benefit to medically needy beneficiaries pursuant to 42 C.F.R. §440.220.

worsening of their conditions, increased physician visits, and hospitalization, and thus increased program costs. Therefore, there is no reason to suppose that legislatures will eliminate pharmacy services altogether from their respective Medicaid programs, and consequently risk enormous cost increases, in order to avoid providing certain medications to beneficiaries.

Indeed, it is clear that the California Legislature, at the time it mandated cutbacks in Medi-Cal pharmacy services, was well aware of its social responsibility to prevent human suffering and of the economic benefit afforded by providing medications to Medi-Cal beneficiaries. Given the fiscal problems which existed in 1982, the Legislature could have eliminated the drug component of the Medi-Cal program at that time. Instead, the Legislature directed the Department of Health Services ("Department") to eliminate primarily those drugs which provided only minor symptomatic relief. Unfortunately the Department violated the law in attempting to do so for, contrary to the prohibition of 42 C.F.R. §440.230(c), it eliminated medications on the basis of diagnosis and illness, making it impossible for physicians to treat certain illnesses and conditions which, if untreated, could cause extreme suffering, serious illnesses and even death among Medi-Cal patients.

C. The Court of Appeal Is Correct in Its Finding that Medi-Cal Beneficiaries Are Entitled to Pre-Denial Hearings With Respect to TARs for Affected Prescription Drugs.

Petioners' second argument, *i.e.*, that the Court of Appeal erred in finding that the TAR system is legally flawed because of its failure to provide pre-denial hearings to

Medi-Cal recipients, is equally unpersuasive. Despite petitioners' lengthy discussion (Pet., pp. 17-25), the simple truth is that the Court of Appeal's finding that a pre-denial hearing is required is well-founded as both a legal and factual matter. As a legal matter, the finding finds overwhelming support in the various California and federal cases cited by the Court of Appeal (*see* Pet. App. A, pp. 19-20), particularly the recent California decisions in *American Federation of Labor v. Employment Dev. Dept.*, 88 Cal.App.3d 811 (1979) and *King v. Woods*, 144 Cal.App.3d 571, 576 (1983). As a factual matter, the finding finds similarly solid support in the evidence contained in the record on appeal, particularly the various declarations submitted to the trial court by plaintiffs in both the *Jeneski* and companion *Fabach* actions.

Significantly, petitioners make no attempt to distinguish away the supporting cases cited by the Court of Appeal, but essentially limit their objection to the Court of Appeal's factual determination. *See* Pet., pp. 20-24. In doing so, however, petitioners misstate and distort the evidentiary record of this case. Most egregious of these misstatements is petitioners' assertion that most of the drugs made subject to prior authorization have equivalents on the Medi-Cal formulary (available without prior authorization) or are readily and cheaply available over-the-counter. *See* Pet., pp. 21-22. The entire basis of the *Jeneski* lawsuit, and a fact that is singularly well-established by the evidentiary record, is that formulary equivalents and inexpensive over-the-counte substitutes are *not* available to Medi-Cal beneficiaries for whom TARs are denied.

Similarly, petitioners' assertion that there is little risk of erroneous and non-arbitrary TAR denials (*see* Pet., pp. 22-23) is wholly contradictory to the overwhelming evidence

submitted both in the *Jeneski* and *Fabach* actions which, as noted by the Court of Appeal (Pet. App. A., p. 7), demonstrated that the overwhelming percentage of TARs for affected drugs were rejected and that such rejections were based upon reasons and criteria that varied depending on the particular Medi-Cal consultant reviewing the TAR.

Finally, petitioners' prediction that the State will face an overwhelming new burden should pre-denial hearings be required (Pet., pp. 23-24) is not only highly speculative, but highly unlikely if, as petitioners represent, an extensive post-denial hearing system is already in place. Surely a mere shift in the timing of the hearing process from post- to pre-denial should make little, is any, difference on the burden the hearing system places on the State.[12]

D. The Court of Appeal Is Correct in Its Finding that the TAR System Is Flawed Since Pharmacists, Instead of Physicians, Make the Ultimate Determinations Concerning Drug Treatment Which Is Medically Necessary for a Patient.

As its final point, petitioners contend that the Court of Appeal erred in its finding that the prior approval process is flawed due to its failure to provide for the review of TAR requests by physicians. *See* Pet., pp. 25-27. In finding the system flawed in this respect, the Court of Appeal reasoned as follows:

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[12] Petitioners' additional argument that the Court of Appeal failed to acknowledge existing *post*-denial appeal procedures is, of course, a matter wholly irrelevant to the proprietary of the Court of Appeal's finding as to the need for *pre*-denial hearing procedures.

> Similarly, in *Dodson v. Parham*, (N.D. Ga. 1977) 427 F.Supp. 97, a case involving reductions in pharmaceuticals to Medicaid patients, the court granted injunctive relief to Medicaid recipients and held that the cutbacks in the Georgia Medicaid program, taken together with a prior approval system that the court considered ineffective, is "medically unsound." (*Id.*, at p. 108.)
>
> One of the elements of the prior approval system found inadequate by the United States District Court in Georgia was that a doctor of pharmacy rather than a physician made the decision in reviewing the prior approval. The court found it "unrealistic for defendants to presume that a doctor of pharmacy is capable of making that type of informed judgment which is necessary to ultimately review any request for prior approval for a drug which the requesting physician in his experience has found to be medically necessary and indicated for a patient with whom is is ultimately familiar. ...[T]he decision must further reflect the practical experience only possessed by one who is skilled in the medical field and perhaps even in certain specialties." (*Id.*, at p. 108.) We find this logic persuasive and agree with amicus curiae that this flaw in the prior approval system invalidates the prior authorization procedures used by [petitioners] herein.

Pet. App. A, p. 18.

Petitioners' complaint that the Court of Appeal cited only the *Dodson* case as authority (*see* Pet., p. 25) for its finding is, of course, irrelevant. The *Dodson* case is good

law, and petitioners acknowledge the truth of the premise of the *Dodson* holding, *i.e.*, that Congress has emphasized physician discretion in the treatment of Medicaid patients. *See* Pet., p. 26.

Petitioners' attempt to distinguish away the *Dodson* case on the grounds that *Dodson* failed to indicate whether certain factors present in the California prior authorization system also existed in the Georgia prior authorization system (*see* Pet., pp. 25-26) is equally unavailing. The *Dodson* court's failure to specify that such factors existed in the Georgia program hardly indicates that they did *not* exist in that program. In any event, the evidence in this case demonstrates overwhelmingly that, despite the presence of the factors in question, *i.e.*, the availability of medical consultants and the existence of specific criteria for reviewing TARs, the decisions rendered by Medi-Cal's pharmacist TAR reviewers were remarkably inconsistent and lackiang in medical soundness.

Finally, petitioners' attempt to characterize the decisions of the pharmacist TAR reviewers as simply ministerial determinations which do not interfere with a physician's choice of proper medical treatment for his patients is disingenuous and utterly improper. Most egregious is the following statement, found on pages 26-27 of the petition:

> Department pharmacists, in ruling on TARs, are not second guessing the treating physician but are merely ensuring that the prescribed drug is reimbursable under the statutory and regulatory limitations which the Legislature and the Department have enacted and promulgated.

What petitioners neglect to point out is that the pharmacist measures the request against a "medically necessary" or "necessary to prevent significant disability or

death" standard for approval. If the physician can satisfy the pharmacist that the proposed drug therapy meets such a requirement then the medication is approved; if he cannot persuade the pharmacist, then the medication is denied.

Clearly, as Congress has mandated, and as the *Dodson* court and the Court of Appeal have found, when a person's health and life are at stake, decisions regarding medical treatment should be delegated to the patient's physician, not a pharmacist employed by a state bureaucracy.

CONCLUSION

This case presents neither a novel question of federal law, nor one which has been decided in conflict with other federal or state appellate courts. Rather, the decision of the Court of Appeal here at issue involves a finding that, on balance, respondents are entitled to preliminary injunctive relief. Moreover, the Court of Appeal's decision is in all respects correct, and is consistent with and fully supported by the decisions of the state and federal appellate courts which have addressed the federal questions presented by this case.

It is respectfully submitted that the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

MARKS AND STEVENSON
RONALD S. MARKS

JONATHAN WEXLER

APPENDIX A

HELEN VANDER STEEN, Petitioner-Respondent, v. DEPARTMENT OF HEALTH AND SOCIAL SERVICES OF THE STATE OF WISCONSIN, Appellant.

NO. 84-047

UNPUBLISHED LIMITED PRECEDENT OPINION

Court of Appeals of Wisconsin
District III

Slip Opinion

November 6, 1984

APPEAL from an order of the circuit court for Brown county: VIVI L. DILWEG, Judge. Affirmed.

Before Foley, P.J., Dean and Cane, JJ.

DEAN, J. The Department of Health and Social Services appeals an order to reinstate medical assistance benefits under secs. 49.43 to 49.497, Stats. The department determined that Helena Vander Steen was ineligible for reimbursement of inpatient nursing care pursuant to sec. 49.45(6m) (i), Stats. The trial court ordered reinstatement on the grounds that the department relied on an improperly promulgated rule in depriving Vander Steen of benefits and that sec. 49.45(6m) (i) violated federally mandated "comparability" requirements. 42 U.S.C. § 1396a(a) (10) (B) (1983). Because we conclude that the statute conflicts with regulations promulgated under the Medicaid Act, Title

XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396-1396i (1983), we affirm.[1]

Vander Steen entered an intermediate care facility on December 3, 1982. As a Supplemental Security Income recipient under federal Title XVI, she was eligible for Medicaid assistance as a categorically needy person. Section 49.46(1) (a) 4, Stats. Intermediate care facility services are an available Medicaid benefit, sec. 49.46(2) (b) 6a, Stats., and Vander Steen received assistance because she was admitted for ICF-1 care, sec. 49.45(6m) (i) 1, Stats. In March, 1983, the department reduced her level of care to ICF-3. Section 49.45(6m) (i) 2, Stats., limits reimbursement of ICF-3 nursing care to those persons who entered a facility before October 1, 1981, or who have a primary diagnosis of developmental disability or chronic mental illness if they entered a facility on or before November 1, 1983. Vander Steen satisfied the November 1, 1983, cutoff. The department, however, concluded that her diagnosis of senility was not within the statutory exceptions permitting reimbursement. Although the ICF-3 level of care includes individuals who are mentally handicapped, disabled from aging, or chronically ill, Wis. Admin. Code §HSS 132.13(13) (a) (1982), reimbursement is limited to the developmentally disabled and the chronically mentally ill. The question is whether this limited exception complies with federal law.

In reviewing a circuit court order reversing a department order, our scope of review is identical to that of the circuit

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[1] Because we conclude that §49.45(6m) (i), Stats., conflicts with the federal law, we do not consider the argument that a department memorandum interpreting the statute is an administrative rule under §227.01(9), Stats., which was not promulgated in accordance with the Administrative Procedure Act.

court. *Boynton Cab Co. v. DILHR*, 96 Wis.2d 396, 405, 291 N.W.2d 850, 855 (1980). Since the issue in this case involves the interpretation and application of federal law, we do not accord the department any deference. *Swanson v. Department of Health and Social Services*, 105 Wis.2d 78, 82-83, 312 N.W.2d 833, 835 (Ct. App. 1981).

Once a state accepts federal Medicaid funds, it must abide by the federal law's purposes and provisions. *Rickaby v. Wisconsin Department of Health and Social Services*, 98 Wis.2d 456, 457, 297 N.W.2d 36, 37 (Ct. App. 1980). Controlling federal law includes the requirements imposed by both the federal statutes and the regulations of the Secretary of Health and Human Services. *Schweiker v. Gray Panthers*, 453 U.S. 34, 37 (1981). One regulation details the permissible and impermissible ways in which a state may exclude or diminish payment for certain services. A state may distinguish between eligible and ineligible recipients of a provided service on the basis of medical need. *Hodgson v. Board of County Commissioners*, 614 F.2d 601, 608 (8th Cir. 1980); 42 C.F.R. §440.230(d) (1983). A Medicaid agency, however, may not arbitrarily deny or reduce a required service's amount, duration, or scope to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition. 42 C.F.R. §440.230(c) (1983).

Section 49.45(6m) (i) denies service solely on the basis of diagnosis. The statute refers specifically to diagnosis as the distinguishing characteristic. There is no indication that the state considered the medical need of the developmentally disabled and the chronically mentally ill under ICF-3 care to be greater than the medical need of patients like Vander Steen. Their need for the same level of care is evidence exactly to the contrary. The department treated Vander Steen differently solely because she suffers from infirmities

of aging rather than developmental disabilities or chronic mental illness. The department's action is improper under the federal regulation.

Intermediate care facility services are a required service. While such services do not form part of a state Medicaid plan's mandatory nucleus for the categorically needy, 42 U.S.C. § 1396a(1) (10) (4) (1983), such services are required by the Wisconsin plan, sec. 49.46(2) (b)6a, Stats. In *White v. 5 5 Beal*, 555 F.2d 1146 (3d Cir. 1977), the regulation was similarly applied to a service required by the Pennsylvania plan that was not specifically mandated by the federal statute. Moreover, intermediate care facilaity services are also required for the medically indigent, sec. 49.47(6) (a), Stats., and federal law required for the medically indigent, sec. 49.47 (6) (a), Stats., and federal law precludes giving less generous aid to the categorically needy than to the medically needy. *Sinclair v. Department of Health and Social Services*, 77 Wis.2d 322, 334, 253 N.W.2d 245, 250 (1977); 42 U.S.C. § 1396a(a) (10) (B) (1983).

There is no argument that Vander Steen is not an otherwise eligible Medicaid recipient. The circuit court, therefore, correctly reversed the department's order and required reinstatement of Vander Steen's medical assistance. While the statute now mandates equal treatment of ICF-3 patients who enter a facility after November 1, 1983, the department cannot discriminate between patients who entered a facility on or before November 1, 1983, solely on the basis of diagnosis.

By the Court. — Order affirmed.

Not recommended for publication in the official reports.

DISPOSITION:

By the Court. — Order affirmed.

Not recommended for publication in the official reports.